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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,453	03/20/2001	R. Rogers Yocum	OGZ-001	3274

959 7590 10/02/2002

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/02/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,453	Applicant(s) YOCUM ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to methods of identifying antibiotics comprising contacting an assay composition comprising a CoaX protein with a test compound and determining the ability of the compound to inhibit CoaX protein activity, classified in class 424, subclass 9.2.

II. Claim 13, drawn to methods of identifying antibiotics comprising contacting an assay composition comprising a CoaX protein with a test compound and determining the ability of the compound to bind CoaX, classified in class 424, subclass 9.2.

III. Claim 14, drawn to methods of identifying antibiotics comprising contacting an assay composition comprising a CoaX protein with a test compound and determining the ability of the compound to inhibit CoaX protein activity, and to bind CoaX, classified in class 424, subclass 9.2.

IV. Claim 15, drawn to methods of identifying antibiotics comprising contacting an assay composition comprising a CoaX protein with a test compound and determining the ability of the compound to modulate the ability of pantothenate to bind CoaX, classified in class 424, subclass 9.2.

V. Claim 16, drawn to methods of identifying antibiotics comprising contacting an assay composition comprising a CoaX protein with a test compound and

determining the ability of the compound to modulate the ability of pantothenate to bind CoaX, and to inhibit CoaX protein activity, classified in class 424, subclass 9.2.

VI. Claim 17, drawn to methods for identifying compounds that modulate pantothenate kinase activity comprising contacting a recombinant cell expressing a single pantothenate kinase encoded by a coax gene with a test compound and determining the compounds ability to modulate the kinase's activity, classified in class 424, subclass 9.2.

VII. Claims 18-25, drawn to methods for identifying compounds that modulate pantothenate kinase activity comprising contacting a recombinant cell expressing a first and a second pantothenate kinase with a test compound and determining the compounds ability to modulate the kinase activity or either the first or second kinase, classified in class 424, subclass 9.2.

VIII. Claims 26, 34, 35, and 36 drawn to isolated nucleic acid molecules comprising a coaX gene, classified in class 536, subclass 23.7.

IX. Claims 27-33, drawn to isolated pantothenate kinase proteins, classified in class 530, subclass 350.

X. Claim 36, drawn to recombinant PA876 microorganism wherein the coaX gene has been deleted, classified in class 435, subclass 252.3.

Group I above comprises multiple patentably distinct inventions and, for this Group, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-X, and, if Group I is elected, to one of inventions (I1)- (I33). These subgroups comprise the methods of the Group I, wherein the CoaX protein is represented by

(I1) SEQ ID NO: 12;
(I2) SEQ ID NO: 70;

(I3) SEQ ID NO: 45;
(I4) SEQ ID NO: 47;
(I5) SEQ ID NO: 49;
(I6) SEQ ID NO: 2;
(I7) SEQ ID NO: 51;
(I8) SEQ ID NO: 53;
(I9) SEQ ID NO: 3;
(I10) SEQ ID NO: 57;
(I11) SEQ ID NO: 8;
(I12) SEQ ID NO: 59;
(I13) SEQ ID NO: 7;
(I14) SEQ ID NO: 61;
(I15) SEQ ID NO: 6;
(I16) SEQ ID NO: 63;
(I17) SEQ ID NO: 4;
(I18) SEQ ID NO: 13;
(I19) SEQ ID NO: 9;
(I20) SEQ ID NO: 15;
(I21) SEQ ID NO: 11;
(I22) SEQ ID NO: 21;
(I23) SEQ ID NO: 55;
(I24) SEQ ID NO: 14;
(I25) SEQ ID NO: 67;
(I26) SEQ ID NO: 43;
(I27) SEQ ID NO: 22;
(I28) SEQ ID NO: 39;
(I29) SEQ ID NO: 41;
(I30) SEQ ID NO: 20;
(I31) SEQ ID NO: 10;
(I32) SEQ ID NO: 65; or
(I33) SEQ ID NO: 5.

Group VII above comprises multiple patentably distinct inventions and, for this Group, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-X, and, if Group VII is elected, to one of inventions (VII1) or (VII2). These subgroups comprise the methods of Group VII, wherein the recombinant cell is:

(VII1) Escherichia coli; or
(VII2) Bacillus subtilis.

Group VIII above comprises multiple patentably distinct inventions and, for this Group, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-X, and, if Group VIII is elected, to one of inventions (VIII1)-(VIII4). These subgroups are inventions wherein the nucleic acid comprises

(VIII1) a B. subtilis coaX (YH1 comprising pOTP71; and PA861);

(VIII2) an H. pylori coaX (YH1 comprising pOTP72);
(VIII3) a P. aeruginosa coaX (YH1 comprising pOTP73); or
(VIII4) a yacB gene (YH1 comprising pAN341).

Group IX above comprises multiple patentably distinct inventions and, for this Group, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-X, and, if Group IX is elected, to one of inventions (IX1)- (IX32). These subgroups comprise the methods of the Group I, wherein the CoaX protein is represented by

(IX1) SEQ ID NO: 12;
(IX2) SEQ ID NO: 45;
(IX3) SEQ ID NO: 47;
(IX4) SEQ ID NO: 49;
(IX5) SEQ ID NO: 2;
(IX6) SEQ ID NO: 51;
(IX7) SEQ ID NO: 53;
(IX8) SEQ ID NO: 3;
(IX9) SEQ ID NO: 57;
(IX10) SEQ ID NO: 8;
(IX11) SEQ ID NO: 59;
(IX12) SEQ ID NO: 7;
(IX13) SEQ ID NO: 61;
(IX14) SEQ ID NO: 6;
(IX15) SEQ ID NO: 63;
(IX16) SEQ ID NO: 4;
(IX17) SEQ ID NO: 13;
(IX18) SEQ ID NO: 9;
(IX19) SEQ ID NO: 15;
(IX20) SEQ ID NO: 11;
(IX21) SEQ ID NO: 21;
(IX22) SEQ ID NO: 55;
(IX23) SEQ ID NO: 14;
(IX24) SEQ ID NO: 67;
(IX25) SEQ ID NO: 43;
(IX26) SEQ ID NO: 22;
(IX27) SEQ ID NO: 39;
(IX28) SEQ ID NO: 41;
(IX29) SEQ ID NO: 20;
(IX30) SEQ ID NO: 10;
(IX31) SEQ ID NO: 65; or
(IX32) SEQ ID NO:5.

The inventions are distinct, each from the others, for the following reasons:

2. The inventions of Groups IX1-IX32 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to isolated proteins. However, although all of the proteins are pantothenate kinases, each of them has a different amino acid sequence. Having different amino acid sequences, the proteins are distinct one from another.

3. The inventions of Groups VIII1-VIII4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of these Groups relate to molecules that encode for different proteins. As the molecules are encoding for different proteins, they are not performing the same function, the molecules are therefore distinct.

4. The inventions of Groups VII1 and VII2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to methods of identifying pantothenate kinase modulating compounds using different bacterial cells. As the methods are not disclosed as usable together, and as testing using different cell types are different modes of operation for a method, the inventions are distinct.

5. The inventions of Groups I1-I33 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions relate to methods of determining the ability of compounds to inhibit the activity of different pantothenate kinase proteins. As each method is determining the effect of a compound on a different protein, the methods are performing different functions. Because the methods are performing different functions, and because they are not disclosed as usable together, the methods are distinct.

6. The inventions of Group III and Group V are related, respectively, as combination and subcombination with Groups I and II, and with Groups I and IV. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each combination comprises subcombinations that are independently claimed. As each combination combines two subcombinations that are independently patentable, neither combination is relying on a single subcombination for its patentability. As the subcombinations are each disclosed as independently useful for the identification of antibiotics, each of the combinations is distinct from each of the subcombinations.

7. The inventions of Groups I, II, and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the subcombinations is disclosed as independently useful for the identification of antibiotics. As the subcombinations are disclosed as separately useful, they are distinct.

8. Inventions of Groups I-V, Group VI, and Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to a different method. The methods of Groups I-V are used to identify antibiotics, while those of groups VI and VII are each different methods of identifying compounds that modulate pantothenate kinase activity. The methods are not disclosed as usable together, and the methods of Groups VI and VII each have different modes of operation (they use different cells, and make different measurements). As the methods are either performing different functions, or are using different modes of operation, the methods are distinct.

9. The inventions of Groups VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to a different composition of matter. Group VIII relates to nucleic acids, Group IX relates to proteins, and Group X relates to a series of microbes. The proteins and nucleic acids each perform different functions, and the microbes of Group X are not disclosed as comprising the molecules of the other two Groups. The products are unrelated, and therefore distinct.

10. The inventions of Group I-VII and of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to methods of identifying antibiotics by

measuring the effect of compounds on ability to bind or inhibit the activity of the CoaX protein, and/or to modulate the ability of pantothenate to bind CoaX, or to DNA encoding CoaX. As the DNA is not used in the methods, the inventions of Group VIII are unrelated to the inventions of Groups I-VII.

11. The inventions of Groups IX and of Groups I-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. MPEP § 806.05(h). In the instant case, the proteins of Group IX may be used for in other methods than those of any of the Groups of methods. The protein may both be used in any of the distinct methods, and can also be used to produce antibodies or to identify bacterial species. As the proteins may be used in other methods, the proteins are distinct from all of the methods of Groups I-VII.

12. The inventions of Group VIII are unrelated to the inventions of Group IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate either to proteins, or to nucleic acids. Proteins and nucleic acids are different types of molecules that perform different functions, have different modes of operation, and have different effects. For example, proteins may be used to create antibodies, to treat diseases, or to bind or inhibit cell receptors. Nucleic acids may be used as hybridization probes, to transform host cells, or to produce polypeptides. Because of those

differences between proteins and nucleic acids, and because they are not disclosed as usable together, the inventions are distinct.

13. Invention X and the inventions of Groups I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to inventions comprising a recombinant microorganism lacking a coaX gene, or to products comprising or methods involving either the coaX gene or CoaX protein. Because the methods do not involve the products of Group X, and the products of Groups VIII and IX have different modes of operation and different function from Group X with respect to the coaX gene or CoaX protein, Group X is distinct from the other Groups of inventions.

Conclusion

14. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See, MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR

> 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

15. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
September 20, 2002

James C. Housel
JAMES HOUSEL 10/1/02
SUPERVISORY PATENT EXAMINER
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